UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, *et al.* Plaintiffs, v. GLAXOSMITHKLINE LLC, Defendant.	Civil Action No. 2:13-cv-4663-JS

DEFENDANT GLAXOSMITHKLINE LLC'S PRE-TRIAL MEMORANDUM

Pursuant to Local Rule 16.1(c) of the Eastern District of Pennsylvania, Defendant GlaxoSmithKline LLC ("GSK") respectfully submits this Pre-Trial Memorandum. GSK respectfully reserves the right to request leave of the Court to amend the information contained herein, upon reasonable notice to the other party.

A. STATEMENT OF THE CASE

The 38 insurer-plaintiffs filed this action in July 2011 based on supposed wrongdoing that allegedly occurred between 2000 and 2005 (the "Relevant Period"). Plaintiffs claim that 17 "At-Issue Drugs"[1] manufactured at a plant in Cidra, Puerto Rico ("Cidra" or "the Plant"), then operated by a GSK affiliate, were not manufactured in compliance with current Good Manufacturing Practices ("cGMPs"). cGMPs are a set of rigorous manufacturing process regulations promulgated and enforced by the Food and Drug Administration (the "FDA"). Plaintiffs do not dispute that their insureds received the therapeutic benefits of the At-Issue

[1] The At-Issue Drugs are: Albenza, Avandia, Avandamet, Bactroban, Compazine, Coreg, Denavir, Dibenzyline, Dyazide, Dyrenium, Factive, Horowitz, Kytril, Paxil IR, Paxil OS, Stelazine, and Thorazine

Drugs. Nor do plaintiffs deny that they themselves made billions of dollars in profits consisting of premiums as a result of covering these drugs. Yet only after having been approached by outside counsel years after the violations alleged occurred, plaintiffs now claim the At-Issue Drugs were "worthless" and that, had they known the drugs supposedly were not manufactured in accordance with cGMPs, they would not have included the drugs in their formularies and reimbursed for them. Plaintiffs have asserted claims for fraud, negligent misrepresentation, statutory insurance fraud, breach of express warranty, and breach of the implied warranty of merchantability.[2]

Plaintiffs' novel theory fails on numerous grounds. *First*, while the FDA identified cGMP violations with respect to some batches of drugs produced at Cidra, plaintiffs adduced no evidence that these issues impacted all drugs manufactured there from 2000 to 2005 or that any drug for which they reimbursed failed to meet its FDA-required specifications, or was unsafe or ineffective. The plaintiffs will have the burden to prove that every drug paid for was affected. *Second*, although the FDA inspected the Plant regularly during the Relevant Period, it permitted the At-Issue Drugs to remain on the market, and plaintiffs testified uniformly that they never remove drugs from their formularies based on manufacturing issues unless the FDA seeks to remove such drugs from the market entirely. *Third*, plaintiffs suffered no injury whatsoever – to the contrary, they **profited** from covering the At-Issue Drugs. *Fourth*, the applicable two and four year statutes of limitation bar plaintiffs' claims.

This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1367.

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[2] The Court granted summary judgment in GSK's favor as to plaintiffs' RICO and unjust enrichment claims.

B. GSK's COUNTER-STATEMENT OF THE FACTS

The FDA "regulates the quality of pharmaceuticals very carefully," and routinely inspects manufacturing facilities for cGMP compliance. SOF ¶ 2; SOF ¶ 5.[3] Given this oversight and the exacting nature of cGMP compliance, it is not surprising that, each year, the FDA issues hundreds of Form 483 observations. SOF ¶ 6. Yet, the FDA rarely removes drugs from the market due to cGMP violations, nor do such drugs forfeit their regulatory approval. Indeed, according to guidance cited by plaintiffs' own experts, the fact that a drug is not manufactured in compliance with cGMPs "does not mean that there is necessarily something wrong with the drug," that the drug is unsafe, or that it is ineffective. SOF ¶ 14.

From 2000 through 2005, the FDA inspected the Cidra Plant at least nine times. These inspections lasted for weeks or months at a time. SOF ¶ 63. During some of these inspections, the FDA identified cGMP violations. SOF ¶¶ 64-76.

In March 2005, the FDA seized outstanding lots of Paxil CR and Avandamet manufactured at the Plant. SOF ¶ 77. In a press release, the FDA explained it "took this action because several inspections of the GSK manufacturing facility where these products are made since 2002 revealed significant violations of FDA's current Good Manufacturing Practice (GMP) regulations at this facility." *Id.* The FDA nonetheless "urged" patients to continue taking these drugs, in consultation with their doctors, because "it is not aware of any harm to consumers by the products subject to this seizure and it does not believe that these products pose a significant health hazard to consumers." SOF ¶ 80. Additionally, the FDA distinguished the seized Paxil CR (not at-issue in this case) from Paxil IR, an At-Issue Drug, and advised patients they could take Paxil IR "with confidence." SOF ¶ 82. The FDA also advised patients to consider taking

[3] References to "SOF" are to Defendant GlaxoSmithKline's Statement of Undisputed Material Facts (D.E. 205).

the At-Issue Drug Avandia, a diabetes drug, if there was a shortage of Avandamet, another diabetes drug consisting in part of Avandia. SOF ¶ 83. The FDA never sought to shutter the Cidra Plant; never initiated proceedings to withdraw its approval of any drug manufactured there; and never asked GSK to stop producing any drug manufactured there (except Avandamet temporarily). *See* SOF ¶ 86.

The sophisticated insurer-plaintiffs "collectively represent approximately 60% of the U.S. market for non-governmental health insurance." SOF ¶ 23. Plaintiffs provide prescription drug coverage under contracts with insured customers and plan sponsors. SOF ¶ 24. During the Relevant Period, plaintiffs generated hundreds of billions of dollars in premium revenue by providing prescription drug coverage to insureds. SOF ¶ 24.

During that time, each plaintiff maintained a formulary or formularies of prescription drugs, which are "lists of drugs covered by health benefit plans administered by plaintiffs." *Id.* ¶ 26. Plaintiffs testified uniformly that they do not consider manufacturing issues, including compliance with cGMPs, in making decisions to include or remove drugs on their formulary. SOF ¶ 55. Indeed, no plaintiff has ever discontinued coverage for any drug, including the At-Issue Drugs, based on cGMP violations except when the FDA removed that drug from the market. SOF ¶ 57. In addition, during the Relevant Period, approximately 97% of private insurance plans used "open" formularies. SOF ¶ 32. These plans contractually obligate the insurer to provide coverage for all FDA-approved drugs. SOF ¶ 33. Due to these contractual obligations, plaintiffs could not simply have removed the At-Issue Drugs from their formularies, as they now claim they would have.

Plaintiffs do not dispute that, although they knew of FDA actions at the plant during the Relevant Period, consistent with their uniform practice of following the FDA's lead,

they took no action to limit availability of the At-Issue drugs. Pls' Resp. to GSK Mot. for S.J. at p. 41 (D.E. 215). No plaintiff discontinued coverage for Paxil CR, Avandamet, or any of the other At-Issue Drugs upon learning of the seizure or the other compliance issues at the Plant. SOF ¶ 142.

Despite knowing of manufacturing issues at the Cidra Plant, no plaintiff ever inquired further. Rather, plaintiffs waited for more than five years after sustaining the last of their supposed injuries to file suit in 2011. And despite demanding recovery of every dollar they paid for the 17 At-Issue Drugs manufactured at the Cidra Plant during the Relevant Period, plaintiffs concede that they do not "intend to prove that the At-Issue Dugs lacked safety and/or effectiveness as to specific patients" and will not present "any proof of patient harm" from them. *Id.* ¶ 175. Nor can plaintiffs establish that they lost even one dollar in premium revenue from having covered the At-Issue Drugs.

C. MONETARY DAMAGES SOUGHT

Plaintiffs have demanded $2.74 billion in compensatory damages. Plaintiffs' damages demand is improperly inflated as they (1) fail to account for the $218,367,446 in rebates they received for the At-Issue Drugs during the Relevant Period; (2) impermissibly include nearly $1 billion in amounts paid by self-funded plans, and not plaintiffs themselves; and (3) fail to deduct the cost of therapeutic alternatives that they undisputedly would have paid for had they removed the At-Issue Drugs from their formularies. Plaintiffs' alleged damages should further be reduced to the extent that they are based on reimbursement of "At-Issue Drugs" made by plaintiffs for their insureds to pharmacies located outside of Pennsylvania.

D. IDENTIFICATION OF WITNESSES

Not knowing how the plaintiffs plan to present their case and meet their burden of proof on each action, defendants are having to over-identify the witnesses that may be needed in defense of this case. With that caveat, GSK identifies the witnesses listed below. GSK reserves the right to call any witnesses listed on Plaintiffs' witness list.

Witness Name	Witness Address	Liability / Damages
Jonathan Box	GSK	Liability
Donald Mackenzie	GSK	Liability
David Pulman	See Plaintiffs' subpoena	Liability
Janice Whitaker	See Plaintiffs' subpoena	Liability
Nilsa Colon-Perez	See Plaintiffs' subpoena	Liability
Kristal Adams	See Plaintiffs' subpoena	Liability
Edna Diaz	See Plaintiffs' subpoena	Liability
Cheryl Meads	See Plaintiffs' subpoena	Liability
Ruth Toledo	See Plaintiffs' subpoena	Liability
Richard Kettlewell	See Plaintiffs' subpoena	Liability
Dr. David Horowitz	Penn Internal Medicine Associates at the Science Center 3701 Market Street 7th Floor, Suite 740 Philadelphia, PA 19104 USA	Liability/Damages
Dr. Gary Owens	P.O. Box 810 Ocean View, DE 19970	Liability
Mr. Ronald Stellon	12 Balmoral Drive Chadds Ford, PA 19317	Liability
Dr. Mohan Rao	Epsilon Economics 111 South Wacker Drive, 50th Floor Chicago, Illinois 60606	Liability/Damages
Michael Brodeur	Aetna	Liability
Myrna Goodrich	Aetna	Liability
Steven Broudy	Amerigroup/HMS	Liability
Leslie Lotano-Saba	Amerigroup/HMS	Liability
Shawn Barger	AvMed Health Plans	Liability
Dorinda Cale	BCBS of Alabama	Liability
Jerry Wong	BCBS of Alabama	Liability

Witness Name	Witness Address	Liability / Damages
David Yoder	BCBS Association	Liability
Allan Korn	BCBS Association	Liability
John Coleman	BCBS of Florida	Liability
Lowell Sterler	BCBS of Florida	Liability
Amy Christensen	BCBS of Kansas City	Liability
Mollie Carby	BCBS of Louisiana	Liability
Milam Ford	BCBS of Louisiana	Liability
Thomas Kowalski	BCBS of Massachusetts	Liability
Randall Hanna	BCBS of Minnesota	Liability
Alan Heaton	BCBS of Minnesota	Liability
Estay Greene	BCBS of North Carolina	Liability
Dan Curran	BCBS of Rhode Island	Liability
Angie Baughman	BCBS of South Carolina	Liability
Robert Giles	BCBS of Tennessee	Liability
Phillip Miller	CareFirst	Liability
Gina Harrison	CareFirst	Liability
Sean Slanger	Caring for Montanans	Liability
John Maesner	CIGNA	Liability
Jameson Reuter	Emblem Health	Liability
Shelby Kirk	GEHA	Liability
Walter Sidles	GHC & KPS	Liability
Scott Wert	Health Net	Liability
Biljana Petreska	HealthNow New York	Liability
Sarah Marche	Highmark, Highmark WV, Highmark BCBS Delaware	Liability
Paul Kaplan	Highmark BCBS Delaware	Liability
John Shoemaker	Medical Mutual of Ohio	Liability
Thomas Christensen	Noridian	Liability
Chad Murphy	Premera	Liability
John Watkins	Premera	Liability
Erica Clark	Priority Health	Liability
Kerry Bendel	Regence Group (Cambia)	Liability
Wendy See	USAble, Health Advantage (HMO Partners)	Liability
Lisa Templeton	Wellcare Health Plans	Liability
Mathew Hosford	Wellmark, Wellmark of Iowa	Liability
Thomas (Jeff) White	Wellpoint	Liability

E. TRIAL EXHIBITS

The Defendant's exhibit list is attached as Exhibit 1. The inclusion of an exhibit on this list does not mean that the exhibit will necessarily be introduced for the truth of the matter(s) asserted in it. In addition, the inclusion of an exhibit on this list does not mean that GSK has waived any objection to the exhibit if offered by Plaintiffs or to the relevance of the subject matter(s) addressed in the exhibit. The parties have stipulated that all exhibits produced by the parties and third parties are authentic. Although this list does not include GSK's demonstrative exhibits, compilations, or summaries, the list includes the sources for any such exhibits. GSK reserves the right to include as an exhibit any document listed on Plaintiffs' exhibit list.

F. TRIAL OF THE CASE

A jury trial is scheduled in this matter to begin on November 12, 2019. GSK estimates that the trial will take approximately six to eight weeks.

G. MISCELLANEOUS ISSUES TO BE ADDRESSED

GSK anticipates raising the following issues at or before the final pre-trial conference:

- The Court's procedures regarding motions for judgment as a matter of law and the timing of such motions
- Right of jurors to take notes
- Notice of witness order and exhibits to be used on direct for fact witnesses
- Supplemental Jury Questionnaire to protect juror confidentiality/HIPAA (proposed form of Questionnaire is attached as Exhibit 2)
- Length of opening and closing presentations
- Briefing regarding disputed jury instructions
- Rulings on motions in limine (final determinations for purposes of FRE 103(b))

- Court's procedures regarding bifurcation of punitive damages phase
- Sequestration of Witnesses and Corporate Representatives
- Court's procedures regarding injunctive relief
- Trial logistics

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